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510(k) Summary of Safety and Effectiveness
May 16, 2001

1.0 Submitter

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Contact: Richard M. Thayer

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K011527

2.0 Device Names

Proprietary Name: Praxsys™ ReLIA™ TSH Test

Common Name: Thyroid Stimulating Hormone Assay

Classification Name: Radioimmunoassay, Thyroid Stimulating Hormone

3.0 Legally Marketed Device

The ReLIA™ TSH Test is substantially equivalent to the Abbott AxSYM® Ultrasensitive hTSH II currently manufactured and distributed by Abbott Laboratories, Abbott Park, IL.

4.0 Device Description

The ReLIA™ TSH Test is a quantitative lateral flow immunoassay for use with the ReLIA™ instrument system. Each test strip is pre-coated with a test band and dual internal control bands and contains necessary reagents to perform an assay. A red line corresponding to the test band indicates the presence of TSH in the sample. For the test to be valid, red lines corresponding to the internal control bands must also appear and must satisfy pre-determined QC acceptance criteria. The ReLIA™ System software utilizes the values of the internal control bands and the test band when determining the test result, expressed in micro international units (uIU/mL). Run-specific QC values are also reported.

To run an assay, the test strips are first pre-conditioned by adding 50ul of sample to sample port one in the test cassette. Once the instrument indicates initialization is complete, an additional 100ul of sample are added to the second sample port. The sample passes through a separation pad and onto a second pad where it solubilizes pre-coated conjugate label. Purified TSH monoclonal antibody as well as antibody to the control reagents are coupled to the conjugate particles. The solubilized sample/conjugate mixture migrates by capillary action across the test and control bands pre-coated on the strip membrane. Excess reagents are taken up by an absorbent pad at the far end of the test strip.

The test band coated on the test strip contains a second purified TSH capture antibody (polyclonal) and the control bands are coated with BSA-dinitrophenyl (BSA-DNP). If TSH antigen is present in the sample added to port 2, it will bind first to the antibody on the labeled conjugate particles and then to the antibody coated on the strip membrane. Likewise, the anti-DNP coupled to the conjugate particles will bind to the BSA-DNP control bands on the test strip.

The ReLIA™ TSH Test is contained in a single-use test cassette designed to run only on the ReLIA™ System, an immunochemistry analyzer that reads, interprets and stores test values and generates both qualitative and quantitative results. The system automatically performs quality control checks, is menu driven, password protected and requires no calibration, specialized training or field service. The barcode present on the test cassette tells the instrument the assay that is being run, the assay expiration date and contains any necessary lot-specific adjustment factors. Optical measurements are taken using a two-channel densitometer.

5.0 Intended Use

The ReLIA™ TSH Test is intended for the quantitative determination of human thyroid stimulating hormone (hTSH) values above 0.5uIU/mL in

human heparinized plasma or human serum on the ReLIA™ System. This assay is intended for use as an aid in the assessment of hypothyroid disease by health care professionals.

6.0 Comparison with Predicate Device

Attribute	Praxsys™ ReLIA™ TSH	Abbott AxSYM® Ultrasensitive hTSH II
Manufacturer	Praxsys Biosystems, Inc.	Abbott Laboratories
Technology	Immunoassay – Lateral Flow	Immunoassay - Microparticle Enzyme Immunoassay
Assay format	Sandwich format monoclonal / polyclonal antibody assay	Sandwich format monoclonal / polyclonal antibody assay
Quantitative	Yes	Yes
Sample Type	Human serum or plasma	Human serum or plasma
Intended Use	Quantitative determination of hTSH values above 0.5uIU/mL in human heparinized plasma or human serum on the ReLIA™ System. Intended for use as an aid in the assessment of hypothyroid disease by health care professionals.	Quantitative determination of hTSH in human serum or plasma on the AxSYM System. The test is used as an aid in the assessment of thyroid status.
Calibration Requirements	No customer calibration. No calibrators required.	Customer calibration required. Master and standard calibrators provided.
Controls	Provided with the ReLIA™ TSH Test kit	Provided separately

7.0 Performance Data

Expected Values (central 95%)
N=72
0.57 – 5.48 uIU/mL

Correlation (versus Abbott AxSYM® Ultrasensitive hTSH II)
N=79
ReLIA™ = 1.0022 x AxSYM – 0.3257
Correlation coefficient (R): 0.98
Tested range: 0.5 – 40 uIU/mL
Mean values: 5.76uIU/mL (ReLIA™) and 6.07uIU/mL (AxSYM)

Precision

A. Within day precision on one instrument:

Standard	n	Avg (uIU/mL)	Std Dev	%CV
1uIU/mL	10	1.04	0.16	15.4
9uIU/mL	10	9.39	0.59	6.3
36uIU/mL	10	36.19	2.17	6.0

B. Within day precision on multiple instruments (10 instruments)

Standard	n	Avg (uIU/mL)	Std Dev	%CV
1uIU/mL	10	0.92	0.17	17.9
9uIU/mL	10	9.48	0.88	9.2
36uIU/mL	10	35.58	2.41	6.8

C. Day-to-day precision on one instrument

Standard	n	Avg (uIU/mL)	Std Dev	%CV
1uIU/mL	10	0.89	0.22	24.7
9uIU/mL	10	9.21	0.87	9.5
36uIU/mL	10	35.94	5.84	16.3

Assay Range

0.5 – 100 uIU/mL

POL Summary Data

120 clinical specimens were collected and run at three physician office sites (40 samples at each site). Duplicate samples were submitted for testing on the predicate device. Following is the correlation determined:

ReLIA™ TSH = 1.0571 x Abbott AxSYM hTSH II + 0.1327
Correlation coefficient (R) = 0.99
Tested Range: 0.52 – 40.14 uIU/mL
Mean Values: 3.91 uIU/mL (ReLIA™) and 3.57 (AxSYM)

Two standard samples were run once per day for 10 days at each of the three physician office sites. Following is a summary of the data:

	Standard 1 (uIU/mL)			Standard 2 (uIU/mL)		
Site	Avg	Std Dev	%CV	Avg	Std Dev	%CV
Site 1	1.04	0.28	26.5	10.82	1.12	10.4
Site 2	1.33	0.22	16.7	10.25	1.58	15.4
Site 3	0.94	0.17	18.3	10.54	1.56	14.8
Total all sites	1.10	0.28	25.1	10.54	1.41	13.3

8.0 Conclusion

Based on the data and information presented, the ReLIA™ TSH test is as safe and effective as, and substantially equivalent in principle and performance to, the currently marketed Abbott AxSYM® Ultrasensitive hTSH II test.

By: Richard M Thayer Date: May 15, 2001

Richard M. Thayer
Vice President
Praxsys Biosystems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
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Re: 510(k) Number: K011527
Trade/Device Name: ReLIA ™ TSH Test
Regulation Number: 862.1690
Regulatory Class: II
Product Code: JLW
Dated: July 27, 2001
Received: July 31, 2001

Dear Mr. Thayer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Applicant: Praxsys Biosystems, Inc.

510(k) Number (if known): ~~not assigned~~ K011527

Device Name: ReLIA™ TSH Test

Indications For Use:

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☒ Prescription Use

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011527